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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TUCKER, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1624	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,948	GYBACK ET AL.	
	Examiner	Art Unit	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 19-65* is/are pending in the application.

4a) Of the above claim(s) *14,15 and 19-28* is/are withdrawn from consideration.

5)☒ Claim(s) *12 and 13* is/are allowed.

6)☒ Claim(s) *1-11 and 29-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*. See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

Applicants' request, pursuant to the correspondence filed 22 January 2007 (hereinafter "present amendment"), that claims 1, 2, 9 and 43-48 be amended and new claims 64 and 65 be added has been honored. The present amendment is in reply to the Office action mailed 20 July 2006 (hereinafter "previous Office action").

Requirement for Restriction

Because the claims drawn to the invention elected for examination, the invention of Group I – chemical compounds of formula I – are not in condition for allowance at this time, the claims drawn to the nonelected inventions of Groups II and III are not rejoined. The Requirement for Restriction as set forth in the Office action mailed to applicants on 22 November 2005 will be withdrawn at such time that rejoinder of Groups II and III occurs. Applicants are reminded that claims of nonelected Group IV – intermediate compounds employed in the preparation of formula I compounds according to invention of Group I – will not be rejoined in this application, regardless, because they are not commensurate in scope with the claims of Group I (see MPEP 806.05(f)). Should a reply to this Office action be submitted, cancellation of claims 26-28 in that reply would be appreciated.

Status of Claim Rejections - 35 USC § 112

In the previous Office action, claims 1, 3-11 and 29-63 were rejected under 35 U.S.C. 112, first paragraph, for recitation of new matter. The proviso stating that the compound 3-amino-5,6,7,8-tetrahydrobenzo[b]pyrazin-2-(N-cyclohexyl)carboxamide is not within the scope of claim 1 was deemed to be new matter. In view of the present amendment to claim 1, which deletes this proviso language, the rejection is hereby withdrawn. Applicants' amendment of the definition of variable R^4 so as to exclude

unsubstituted amino as an identity of that variable is noted. This amendment does not introduce new matter, as applicants' counsel states in the accompanying remarks.

In the previous Office action, the rejection of claims 1-4 under 35 U.S.C. 112, second paragraph, for being indefinite in scope, was maintained. Since claims 5—11 and 29-63 depend from claims 1 or 2 in the alternative, those claims are in turn indefinite in scope as well. On the "Office Action Summary" form, the PTO-326 cover sheet to the previous Office action, all claims 1-11 and 29-63 were indicated as having been rejected. It appears that applicants have understood (correctly) that the indefiniteness rejection applies to all claims that depend from another claim which has been rejected as indefinite.

Specifically, the rejection was on the grounds that "C_{0-3}alkylhydroxy" and "C_{0-3}alkyldimethylamino," recited in the definitions provided in claim 1 for variables R^2 and R^4, were not clear when the subscript for the number of carbon atoms (the capital "C" in the terms) is zero. The basis of the rejection is fully explained on pages 4 and 5 of the previous Office action, and page 7 of the non-final Office action mailed 3 March 2006.

In the definition of variable R^3 of claim 1, the terms "C_{1-3}alkanol" and "C_{0-3}alkylOC_{2-4}alkanol" were also deemed to be indefinite. An *alkanol* is a compound in and of itself, a simple alcohol, for example methanol, ethanol, propanol. Therefore an alkanol cannot be a substituent on a molecule; it possesses no vacant bonding orbitals (nowhere it may be bonded to some other molecular fragment). The latter term noted in the beginning of this paragraph is not understood because it also describes a molecular structure in and of itself. An alkyl-O-alkanol would be an alkoxy-substituted alcohol, and cannot be a substituent group on a molecule.

In view of the present amendment to claims 1 and 2, which deletes the terms "C_{0-3}alkylhydroxy" and "C_{1-3}alkanol," the rejection is withdrawn *in part*. The term "hydroxyC_{1-}

$_3$alkyl" has been introduced in place of "C_{1-3}alkanol," which poses no indefiniteness problems. The meaning of the term "hydroxyC_{1-3}alkyl" is clear. Claim 2 no longer recites any of the terms deemed to be indefinite in the previous Office action.

The indefinite term "C_{0-3}alkyldimethylamino" remains in the definition of R^2 in claim 1. Rejection of this term as being indefinite was traversed by applicants, the argument being that it is clear that "C_{0-3}alkyldimethylamino" refers to a dimethylamino group bearing an optional *third* alkyl group, in addition to the two methyl groups already present, which alkyl group is composed of from one to three carbon atoms. Although the remarks submitted by applicants does not reference the term "quaternary ammonium" in connection with "C_{0-3}alkyldimethylamino," what is in essence being described is a quaternary ammonium function – an amino nitrogen bonded to the amide nitrogen atom, OF R^2 and further bonded to three (3) alkyl groups. In the previous Office action, the examiner indicated that this might be one of the possible interpretations of the term (see page 5), and if this was so, then what the term actually describes is a quaternary ammonium group. A quaternary ammonium group bears a formal positive (+) charge, and must be represented as such, to avoid ambiguity. Because the quaternary ammonium group which is optionally one of the identities of R^2 (according to the argument traversing the rejection) does not clearly define the quaternary ammonium function as being positively charged, the term "C_{0-3}alkyldimethylamino" is indefinite. It is not clear if applicants are aware that an amino nitrogen atom cannot bear four bonding partners and be electronically neutral, as represented in the claims. If "C_{0-3}alkyldimethylamino" indeed is optionally a quaternary ammonium function, it must be unambiguously represented as such.

A new term, "C_{0-3}alkylOhydroxyC_{2-4}alkyl" has been introduced into the definition of variable R^3 in claim 1. This new term is not understood, because it seems to describe a

bonding arrangement wherein two oxygen atoms are bonded to one another – the "O" is immediately adjacent to the term "hydroxy." Such a structure would be an alkyl-peroxide group. There appears to be no peroxide compounds in the description of the invention, so this term renders the scope of the claims ambiguous.

Each recitation of "C_{0-3}alkylhydroxy" has been replaced with " C_{1-3}alkoxy, hydroxy..." Although C_{1-3}alkoxy is clear and well-defined, the term "hydroxy" as an alternative definition for R^2 and R^4 is not supported in the disclosure. Nowhere in the written description of the present invention is "hydroxy" (-OH) taught as an identity for these two variables. A rejection of claim 1 (and all claims which depend therefrom), under the first paragraph of 35 U.S.C. 112, for new matter, appears in the following.

In summary, the rejection of claims 1, 3-11 and 29-63 as being indefinite under 35 U.S.C. 112, is maintained, for reasons given hereinabove. New claims 64 and 65 are also rejected under 35 U.S.C. 112, second paragraph, because those two claims depend from claim 1 in the alternative, which is indefinite. The terms "C_{0-3}alkyldimethylamino" and "C_{0-3}alkylOhydroxyC_{2-4}alkyl" are indefinite in claim 1.

Claim 2 has been amended so as to overcome the indefiniteness rejection set forth in the previous Office action, but has been rendered indefinite by the present amendment, which is explained in the following:

Amendment to the definition of ring "Q" in claim 2, which deletes the optional language referring to its being saturated or partially unsaturated, introduces the language "saturated or partially saturated" therein. Exactly what constitutes a "partially saturated" ring, however, in the context of the instant claims is not clear from a reading of the specification. In fact, the term does not appear anywhere in connection with the description of the present invention. "Partially saturated" renders claim 2 indefinite in

scope because it is not clear how that term differs in its meaning, if at all, from "partially unsaturated," which is the definition of "Q" in claim 1, the other independent claim in the application. Furthermore, the absence of "partially saturated" in the instant specification speaks to its indefiniteness when read in light of the specification.

In addition to the rejection of those claims set forth in the preceding, claims 9 and 43-48 are rejected under 35 U.S.C. 112, second paragraph, for indefiniteness, insofar as those claims depend from claim 2. The language "wherein Q is a saturated or partially unsaturated ring" does not find antecedent basis in instant claim 2, from which the indicated claims depend in the alternative. Claim 2 defines ring Q as a "saturated or *partially saturated* ring..."

Status of Claim Rejections - 35 USC § 102

Claim 2-11 and 29-63 were rejected under 35 U.S.C. 102(b) in the previous Office action as being anticipated by WO 99/26927 (Van Vagenen et al).

The present amendment to claim 2, which now requires "Q" to be saturated or partially saturated (*vide supra et infra*, for rejections pertaining to this new claim limitation) has overcome the rejection. All of the compounds disclosed in Van Wagenen et al feature a completely unsaturated quinoxaline ring system, not within the scope of the instant claims as presently amended.

New Claim Rejections - 35 USC § 112

Claims 1, 3-6, 9-11, 29-41, 43-46, 49-52, 55-59, 62, 63 and 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

the inventors, at the time the application was filed, had possession of the claimed invention.

By virtue of the present amendment, the variables R^2 and R^4 are now permitted to be hydroxy or C_{1-3}alkoxy in the alternative. Nowhere in the instant specification or claims, as originally filed, was "C_{1-3}alkoxy" or "hydroxy" set forth as a permissible identity for either of these variables. No support appears in the instant specification for R^2 and R^4 being C_{1-3}alkoxy or hydroxy. An amendment to the specification, at the appropriate points wherein variables R^2 and R^4 are defined, that introduces corresponding language such as was introduced into claim 1 in connection with R^2 and R^4 would overcome this new matter rejection. This amendment would not be viewed as new matter because the term "C_{0-3}alkylhydroxy" could be interpreted as contemplating an unsubstituted hydroxyl group or C_{1-3}alkoxy but since neither term is set out in the written description of the invention, the terms do not find support.

Claims 2-11, 29-42, 49-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The term "partially saturated" which now describes one of the alternative generic definitions of the "Q' ring in claim 2, by virtue of the present amendment, is not found anywhere in the claims or specification as originally filed.

Allowable Subject Matter

Claims 12 and 13 are allowed, for reasons given in the previous Office action, and in the Office action mailed 3 March 2006.

Claims 1-11 and 29-65 would be overcome if the rejections under 35 U.S.C. 112, first and second paragraphs were overcome.

Amendment of the method-of-treatment claims which are presently withdrawn is recommended, so that treatments of only schizophrenia, epilepsy and pain are recited. At the time the invention was made, the state of the art with respect to therapeutic application of mGlur antagonists was such that only treatment of these three indications was plausible and understood by a physician of ordinary skill. A reference was cited in the previous Office action, authored by Ritzén et al, which provides evidence of this fact.

Should method-of-treatment claims be in condition such that rejoinder thereof would present new patentability issues when and if a response to this Final Office Action is received, the amendment will be denied entry (MPEP 821.04(b).

The process according to claim 25, similarly, should be amended if applicants wish for rejoinder thereof, upon placing claims of the elected invention in condition for allowance.

In alternative "A," the language "...with an activating agent followed by the treatment of the resulting acid halide, or otherwise to nucleophiles activated acid derivative,..." appears. First, the activating agent does not necessarily produce an acid halide, second, "nucleophiles activated acid derivative" is not a term of art, nor is it defined to any degree of specificity in the instant specification. Amendment of "A" in claim 25 such that the language "...with an activating agent followed by the treatment of the resulting acid halide, or otherwise to nucleophiles activated acid derivative,..." is replaced with "...with an activating agent, followed by the treatment of the resulting activated carboxylic acid derivative..." would obviated this issue.

In alternative "C," the step of "reacting a compound of formula VIa... with an appropriate amine such as the compound of formula XIV..." appears in claim 25. This limitation does not require the formula XIV compound to be a reactant in the process according to claim 25. Claim 25 is provisionally deemed to be indefinite, because the structure of the compound produced when the "appropriate amine' is *not* a compound of formula XIV is unknown. Deletion of the phrase "with an appropriate amine such as the compound of formula XIV" and replacing it with "with a compound of formula XIV" would obviate this issue.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 5:45am to 2:15pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

ZACHARY C. TUCKER
PRIMARY EXAMINER